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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 200.1079CON4

SERIAL NO.: Not yet known  
10/056,348

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE: Herewith

GROUP: Not Yet Known

1639

## U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME            | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|-------------------|----|-----------------|---|---|---|---|---|---|----------|-----------------|-------|----------|----------------------------|
|                   | AA | 5               | 8 | 5 | 9 | 2 | 5 | 7 | 01/12/99 | Talley          | 548   | 247      | 08/14/98                   |
|                   | AB | 5               | 8 | 6 | 3 | 9 | 2 | 2 | 01/26/99 | Mayer, et al.   | 514   | 270      | 07/02/99                   |
|                   | AC | 5               | 8 | 4 | 0 | 7 | 3 | 1 | 11/24/98 | Mayer, et al.   | 514   | 289      | 08/02/95                   |
|                   | AD | 5               | 8 | 6 | 9 | 4 | 9 | 8 | 02/09/99 | Mayer, et al.   | 514   | 282      | 07/07/97                   |
|                   | AE | 5               | 8 | 6 | 1 | 4 | 1 | 9 | 01/19/99 | Dube, et al.    | 514   | 334      | 07/11/97                   |
|                   | AF | 5               | 7 | 8 | 9 | 4 | 1 | 3 | 08/04/98 | Black, et al.   | 514   | 255      | 01/21/97                   |
|                   | AG | 5               | 6 | 0 | 4 | 2 | 6 | 0 | 02/18/97 | Guay, et al.    | 514   | 605      | 11/04/93                   |
|                   | AH | 5               | 4 | 5 | 8 | 8 | 7 | 9 | 10/17/95 | Singh, et al.   | 424   | 400      | 09/30/94                   |
|                   | AI | 5               | 5 | 1 | 6 | 8 | 0 | 3 | 05/14/96 | Raffa           | 514   | 570      | 03/01/95                   |
|                   | AJ | 5               | 8 | 4 | 3 | 4 | 6 | 8 | 12/01/98 | Burkoth, et al. | 424   | 448      | 05/13/98                   |

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |   |
|--|----|---|
|  | AK | Differential Inhibition of Cyclooxygenase-1 (COX-1) and -2 (COX) By NSAIDS: Consequences on Anti-Inflammatory Activity Versus Gastric and Renal Safety, M. Pairet, et al., Inflammopharmacology 4: 61-70, (1996).                                     |
|  | AL | Differential effects of inhibitors of cyclooxygenase (cyclooxygenase 1 and cyclooxygenase 2) in acute inflammation, Derek W. Gilroy, et al. European J. Pharm 355 pp 211-217, (1998).   |
|  | AM | Cyclooxygenases 1 and 2, J.R. Vane, et al. Annu. Rev. Pharmacol. Toxicol. 38: 97-121, (1998).   |
|  | AN | Analysis of the effects of cyclooxygenase (COX)-1 and COX-2 in spinal nociceptive transmission using indomethacin, a non-selective COX inhibitor, and NS-398, a COX-2 selective inhibitor, Tatsuo Yamamoto, et al. Brain Research 739:104-110, (1996) |
|  | AO | Comparative Analgesic Efficacy of Nimesulide and Diclofenac Gels after Topical Application on the Skin, S. Sengupta, et al., Skin Pharmacol. And Applied Skin Phys. 11:273-278, (1998).   |
|  | AP | Carageenan-induced hyperalgesia is associated with increased cyclo-oxygenase-2 expression in spinal cord, Carina Hay and Jacqueline de Belleruche, Neuro Report 8, 1249-1251, (1997).   |
|  | AQ | The Mechanisms of Action of NSAIDs in Analgesia, Jeremy N. Cashman, Drugs 52 Supp. 5:13-23, (1996).   |
|  | AR | Differential effects of inhibition of isoforms of cyclooxygenase (COX-1, COX-2) in chronic inflammation, O.W. Gilroy, et al. Inflamm. Res. 47:79-85, (1998).  |
|  | AS | Constitutive Cyclooxygenase (COX-1) and Inducible Cyclooxygenase (COX-2): Rationale for Selective Inhibition and Progress to Date, Don E. Griswold and Jerry L. Adams, Medicinal Research Reviews, Vol. 16, No. 2, pp. 181-208, (1996).               |

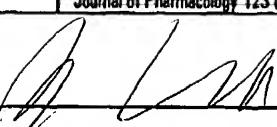
EXAMINER

DATE CONSIDERED

6/30/04

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| FORM PTO-1449<br>(REV. 7-80)  |  |                 | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE |         | ATTY. DOCKET NO.: 200.1079CON4 | SERIAL NO.: Not Yet Known<br>10/056,348 |                            |
|---|--|-----------------|--|---------|--------------------------------|---|----------------------------|
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary)   |  |                 | APPLICANT(S): Ronald M. BURCH, et al.                      |         |                                |   |                            |
|   |  |                 | FILING DATE: Not Yet Known                                 |         | GROUP: Not Yet Known<br>1639   |   |                            |
| U.S. PATENT DOCUMENTS   |  |                 |  |         |                                |   |                            |
| *EXAMINER INITIAL   |  | DOCUMENT NUMBER | DATE   | NAME    | CLASS                          | SUBCLASS                                | FILING DATE IF APPROPRIATE |
| BA  |  |                 |  |         |                                |   |                            |
| BB  |  |                 |  |         |                                |   |                            |
| BC  |  |                 |  |         |                                |   |                            |
| BD  |  |                 |  |         |                                |   |                            |
| BE  |  |                 |  |         |                                |   |                            |
| BF  |  |                 |  |         |                                |   |                            |
| BG  |  |                 |  |         |                                |   |                            |
| BH  |  |                 |  |         |                                |   |                            |
| BI  |  |                 |  |         |                                |   |                            |
| BJ  |  |                 |  |         |                                |   |                            |
| BK  |  |                 |  |         |                                |   |                            |
| FOREIGN PATENT DOCUMENTS  |  |                 |  |         |                                |   |                            |
|   |  | DOCUMENT NUMBER | DATE   | COUNTRY | CLASS                          | SUBCLASS                                | TRANSLATION                |
|   |  |                 |  |         |                                |   | YES                        |
|   |  |                 |  |         |                                |   | NO                         |
| BL  |  |                 |  |         |                                |   |                            |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |  |                 |  |         |                                |   |                            |
| BM  | Cyclooxygenase in biology and disease, Raymond N. Dubois, et al., FASEB J. Vol. 12 pp. 1063-1073 (1998).   |                 |  |         |                                |   |                            |
| BN  | Pharmacology of Meloxicam, A new Non-Steroidal Anti-Inflammatory Drug With An Improved Safety Profile Through Preferential Inhibition of COX-2, G. Engelhardt, British J. Rheumatology, 35 (supp 1):4-12, (1996)   |                 |  |         |                                |   |                            |
| BO  | Cyclooxygenase 1 Contributes to Inflammatory Responses in Rats and Mice: Implications for Gastrointestinal Toxicity, John L. Wallace, et al. Gastroenterology, 115:101-109 (1998).                                 |                 |  |         |                                |   |                            |
| BP  | Distinct Isoforms (COX-1 and COX-2) of cyclooxygenase: possible physiological and therapeutic implications, M. Pairet and G. Engelhardt, Fundam. Clin. Pharmacol. 10:1-15, (1996).                                 |                 |  |         |                                |   |                            |
| BQ  | Involvement of Prostaglandins Produced by Cyclooxygenase-1 in Murine Viscernonociception Induced by Phenylquinone, Hidenobu Kusuvara, et al. Prostaglandins 55: 43-49, (1998).                                     |                 |  |         |                                |   |                            |
| BR  | Effect of COX-1 and COX-2 Inhibition on Induction and Maintenance of Carrageenan-Induced Thermal Hyperalgesia in Rats. D. Dirig, et al. J. Pharmacol. And Experimental Therapeutics Vol. 285, No. 3, pp 1031-1038. |                 |  |         |                                |   |                            |
| EXAMINER  | DATE CONSIDERED<br>6/30/04   |                 |  |         |                                |   |                            |
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|---|---|--|---|---------------------------------------|------|---|-------|----------|----------------------------|----|--|--|
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| U.S. PATENT DOCUMENTS   |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| *EXAMINER INITIAL   |   | DOCUMENT NUMBER  |   |                                       | DATE | NAME                                    | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |    |  |  |
| CA  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CB  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CC  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CD  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| FOREIGN PATENT DOCUMENTS  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
|   |   | DOCUMENT NUMBER  |   |                                       | DATE | COUNTRY                                 | CLASS | SUBCLASS | TRANSLATION                |    |  |  |
| CE  |   | 9  | 9 | 0                                     | 7    | 4                                       | 1     | 3        | 2/18/99                    | WO |  |  |
| CF  |   | 9  | 9 | 3                                     | 2    | 1                                       | 1     | 9        | 7/1/99                     | WO |  |  |
| CG  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CH  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CI  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CJ  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CK  | Effect of meloxicam on postoperative pain after abdominal hysterectomy, J.P. Thompson et al. British Journal of Anaesthesia 84 (2) 151-4 (2000).  |  |   |                                       |      |   |       |          |                            |    |  |  |
| CL  | Intrathecal cyclooxygenase inhibitor administration attenuates morphine antinociceptive tolerance in rats. C.S. Wong et al., British Journal of Anaesthesia 85 (5) 747-51 (2000).                             |  |   |                                       |      |   |       |          |                            |    |  |  |
| CM  | Cyclooxygenase inhibitors increase morphine effects on mesolimbic dopamine neurons, M. Melis, et al. Eur. J. Pharmacology 387 (1) R1-R3 (2000).   |  |   |                                       |      |   |       |          |                            |    |  |  |
| CN  | Synergistic antiallodynic effects of spinal morphine with ketorolac and selective COX-1 and COX-2 inhibitors in nerve-injured rats, J.M. Lashbrook, et al. Pain 82 (1) 65-72 (1999).                          |  |   |                                       |      |   |       |          |                            |    |  |  |
| CO  | Enhancement of opioid inhibition of gaba-ergic synaptic transmission by cyclo-oxygenase inhibitors in rat periaqueductal grey neurones, Vaughn et al. British Journal of Pharmacology 123 (8) 1479-81 (1998). |  |   |                                       |      |   |       |          |                            |    |  |  |
| EXAMINER  |    |  |   |                                       |      | DATE CONSIDERED                         |       |          |                            |    |  |  |
|   |   |  |   |                                       |      | 4/30/07                                 |       |          |                            |    |  |  |
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| FORM PTO-1449<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE |    | ATTY. DOCKET NO.: 200.1078CON4        |    | SERIAL NO.: Not Yet Known<br>10/056,348 |         |                 |          |                               |     |     |          |
|---|----|--|----|---------------------------------------|----|---|---------|-----------------|----------|-------------------------------|-----|-----|----------|
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary) |    |  |    | APPLICANT(S): Ronald M. BURCH, et al. |    |   |         |                 |          |                               |     |     |          |
|   |    |  |    | FILING DATE: Not Yet Known            |    | GROUP: Not Yet Known<br>1639            |         |                 |          |                               |     |     |          |
| U.S. PATENT DOCUMENTS   |    |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| *EXAMINER<br>INITIAL  |    | DOCUMENT NUMBER  |    |                                       |    | DATE                                    | NAME    | CLASS           | SUBCLASS | FILING DATE<br>IF APPROPRIATE |     |     |          |
|   |    | DA   | 5  | 4                                     | 7  |   |         |                 |          |                               | 4   | 9   | 9        |
|   | DA | 5  | 6  | 8                                     | 1  | 3                                       | 7       | 4               | 12/12/95 | Ducharme et al.               | 514 | 241 | 01/10/94 |
|   | DB |  |    |                                       |    |   |         |                 | 11/25/97 | Black et al.                  | 514 | 473 | 05/18/95 |
|   | DC |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DD |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DE |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DF |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DG |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DH |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DI |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DJ |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DK |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| FOREIGN PATENT DOCUMENTS  |    |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   |    | DOCUMENT NUMBER  |    |                                       |    | DATE                                    | COUNTRY | CLASS           | SUBCLASS | TRANSLATION                   |     |     |          |
|   |    | DL   | DM | DN                                    | DO |   |         |                 |          | DP                            | YES | NO  |          |
|   | DL |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DM |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DN |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DO |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
|   | DP |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)        |    |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| DO  |    |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| OR  |    |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| DS  |    |  |    |                                       |    |   |         |                 |          |                               |     |     |          |
| EXAMINER  |    |  |    |                                       |    |   |         | DATE CONSIDERED |          |                               |     |     |          |
| <i>RLM</i>  |    |  |    |                                       |    |   |         | <i>4/30/94</i>  |          |                               |     |     |          |

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| FORM PTO-1448<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |   |   |   |   |   |   | ATTY. DOCKET NO.: 200.1079CON4        | SERIAL NO.: Not Yet Known<br>10/056,348 |       |          |                                     |                                     |
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| LIST OF PRIOR ART CITED BY APPLICANT<br>(Use several sheets if necessary) |    |   |   |   |   |   |   |   | APPLICANT(S): Ronald M. BURCH, et al. |   |       |          |                                     |                                     |
|   |    |   |   |   |   |   |   |   | FILING DATE: Not Yet Known<br>1639    |   |       |          |                                     |                                     |
| U.S. PATENT DOCUMENTS   |    |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
| *EXAMINER INITIAL   |    | DOCUMENT NUMBER   |   |   |   |   |   |   | DATE                                  | NAME                                    | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE          |                                     |
| <i>MM</i>   | EA | 3   | 8 | 0 | 0 | 0 | 4 | 1 | 03/26/74                              | Miller, et al.                          | 424   | 273      | 03/02/71                            |                                     |
|   | EB | 4   | 3 | 2 | 2 | 4 | 2 | 7 | 03/30/82                              | Buyinski, et al.                        | 424   | 280      | 04/16/81                            |                                     |
|   | EC | 4   | 3 | 3 | 8 | 3 | 2 | 4 | 08/06/82                              | Gardocki                                | 424   | 266      | 03/17/81                            |                                     |
|   | ED | 4   | 4 | 0 | 4 | 2 | 1 | 0 | 09/13/83                              | Schmidt                                 | 424   | 260      | 06/30/82                            |                                     |
|   | EE | 4   | 4 | 0 | 7 | 8 | 0 | 4 | 10/04/83                              | Schmidt                                 | 424   | 260      | 06/30/82                            |                                     |
|   | EF | 4   | 4 | 0 | 7 | 8 | 0 | 5 | 10/04/83                              | Schmidt                                 | 424   | 260      | 06/30/82                            |                                     |
|   | EG | 4   | 4 | 6 | 4 | 3 | 7 | 6 | 08/07/84                              | Sunshine, et al.                        | 424   | 253      | 10/11/83                            |                                     |
|   | EH | 4   | 4 | 8 | 6 | 4 | 3 | 6 | 12/04/84                              | Sunshine, et al.                        | 424   | 253      | 03/11/83                            |                                     |
| <i>MM</i>   | EI | 4   | 4 | 8 | 9 | 0 | 8 | 0 | 12/18/84                              | Lomen                                   | 424   | 260      | 12/06/82                            |                                     |
| FOREIGN PATENT DOCUMENTS  |    |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   |    | DOCUMENT NUMBER   |   |   |   |   |   |   | DATE                                  | COUNTRY                                 | CLASS | SUBCLASS | TRANSLATION                         |                                     |
|   |    |   |   |   |   |   |   |   |                                       |   |       |          | YES                                 | NO                                  |
|   | EJ | 2   | 0 | 2 | 3 | 3 | 4 | 9 | 02/18/91                              | Canada                                  | A61K  | 31/44    | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
|   | EK | 0   | 2 | 7 | 4 | 8 | 4 | 5 | 07/20/88                              | EP (A1)                                 | A61K  | 31/19    | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
|   | EL | 0   | 3 | 8 | 8 | 1 | 2 | 5 | 09/18/90                              | EP (A1)                                 | A61K  | 31/485   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)    |    |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   | EM | Pharmacokinetics and Drug Input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration A. Hansen, et al. Arzneim-Forsch./Drug Res. 46 (II) 57-63 (1996).                                 |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   | EN | Comparison of a Standard Ibuprofen Treatment Regimen with a New Ibuprofen/Paracetamol/Codeine Combination in Chronic Osteo-arthritis G.K. Vlok, et al. Univ. Stellenbosch and Tygerberg Hospital, Dept. Orthopaedic Surg. pp 3-6, (1987). |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   | EO |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   | EP |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   | EO |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
|   | ER |   |   |   |   |   |   |   |                                       |   |       |          |                                     |                                     |
| EXAMINER <i>MM</i>  |    |   |   |   |   |   |   |   | DATE CONSIDERED <i>6/30/04</i>        |   |       |          |                                     |                                     |

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|   |    |  |   |   |   |   |   | FILING DATE: Not Yet Known            |          | GROUP: Not Yet Known<br>1639            |          |                            |          |
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| *EXAMINER INITIAL   |    | DOCUMENT NUMBER  |   |   |   |   |   | DATE                                  | NAME     | CLASS                                   | SUBCLASS | FILING DATE IF APPROPRIATE |          |
| <i>MJ</i>   | FA | 4  | 5 | 6 | 7 | 1 | 8 | 3                                     | 01/28/86 | Sunshine, et al.                        | 514      | 264                        | 12/12/83 |
|   | FB | 4  | 5 | 6 | 9 | 9 | 3 | 7                                     | 02/11/86 | Baker, et al.                           | 514      | 282                        | 02/11/83 |
|   | FC | 4  | 5 | 7 | 1 | 4 | 0 | 0                                     | 02/18/86 | Arnold                                  | 514      | 282                        | 12/18/84 |
|   | FD | 4  | 5 | 8 | 7 | 2 | 5 | 2                                     | 05/06/86 | Arnold                                  | 514      | 282                        | 12/18/84 |
|   | FE | 4  | 6 | 1 | 9 | 9 | 3 | 4                                     | 12/28/86 | Sunshine, et al.                        | 514      | 277                        | 07/08/85 |
|   | FF | 4  | 6 | 9 | 0 | 9 | 2 | 7                                     | 09/01/87 | Voss, et al.                            | 514      | 282                        | 02/03/88 |
|   | FG | 4  | 8 | 3 | 9 | 1 | 7 | 6                                     | 06/13/89 | Pahkhania, et al.                       | 424      | 465                        | 12/08/87 |
|   | FH | 4  | 8 | 4 | 4 | 9 | 0 | 7                                     | 07/04/89 | Elger, et al.                           | 424      | 465                        | 08/14/88 |
|   | FI | 4  | 9 | 2 | 7 | 8 | 5 | 4                                     | 05/22/90 | Sunshine, et al.                        | 514      | 570                        | 08/21/89 |
|   | FJ | 5  | 1 | 6 | 4 | 3 | 9 | 8                                     | 12/17/92 | Sims, et al.                            | 514      | 282                        | 04/01/91 |
| <i>MJ</i>   | FK | 5  | 1 | 9 | 0 | 9 | 4 | 7                                     | 03/02/93 | Riess, et al.                           | 514      | 282                        | 08/16/91 |
|   | FL | 5  | 2 | 4 | 0 | 6 | 9 | 4                                     | 08/31/93 | Gwaltney, Jr.                           | 424      | 45                         | 12/19/91 |
| FOREIGN PATENT DOCUMENTS  |    |  |   |   |   |   |   |                                       |          |   |          |                            |          |
|   |    | DOCUMENT NUMBER  |   |   |   |   |   | DATE                                  | COUNTRY  | CLASS                                   | SUBCLASS | TRANSLATION                |          |
|   |    |  |   |   |   |   |   |                                       |          |   |          | YES                        | NO       |
| <i>MJ</i>   | FM | 0  | 0 | 6 | 8 | 8 | 3 | 8                                     | 06/25/82 | EP (A1)                                 | A61K     | 31/485                     |          |
|   | FN | 0  | 0 | 6 | 8 | 8 | 3 | 8                                     | 06/25/82 | EP (B1)                                 | A61K     | 31/485                     |          |
|   | FO | 2  | 0 | 8 | 1 | 6 | 0 | 4                                     | 05/01/85 | Canada                                  | A61K     | 031/135                    |          |
|   | FP |  |   |   |   |   |   |                                       |          |   |          |                            |          |
|   | FQ |  |   |   |   |   |   |                                       |          |   |          |                            |          |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)    |    |  |   |   |   |   |   |                                       |          |   |          |                            |          |
|   | FR |  |   |   |   |   |   |                                       |          |   |          |                            |          |
|   | FS |  |   |   |   |   |   |                                       |          |   |          |                            |          |
|   | FT |  |   |   |   |   |   |                                       |          |   |          |                            |          |
| EXAMINER  |    |  |   |   |   |   |   | DATE CONSIDERED                       |          |   |          |                            |          |
| <i>MJ</i>   |    |  |   |   |   |   |   | 4/30/94                               |          |   |          |                            |          |

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| FORM PTO-1449<br>(REV. 7-80)  |           | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |   |   |   |                              |                 |      | ATTY. DOCKET NO.: 200.1079CON4 | SERIAL NO.: Not Yet Known<br>10/056,348 |          |                            |          |
|---|-----------|--|---|---|---|------------------------------|-----------------|------|--------------------------------|---|----------|----------------------------|----------|
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary)   |           | APPLICANT(S): Ronald M. BURCH, et al.  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   |           | FILING DATE: Not Yet Known   |   |   |   | GROUP: Not Yet Known<br>1639 |                 |      |                                |   |          |                            |          |
| U.S. PATENT DOCUMENTS   |           |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
| *EXAMINER INITIAL   |           | DOCUMENT NUMBER  |   |   |   |                              |                 | DATE | NAME                           | CLASS                                   | SUBCLASS | FILING DATE IF APPROPRIATE |          |
| <i>MM</i>   | GA        | 5  | 4 | 0 | 9 | 9                            | 4               | 4    | 04/25/95                       | Black, et al.                           | 514      | 359                        | 03/12/93 |
|   | GB        | 5  | 4 | 3 | 8 | 2                            | 6               | 5    | 06/25/95                       | Black, et al.                           | 514      | 420                        | 11/12/93 |
|   | GC        | 5  | 5 | 1 | 0 | 3                            | 6               | 8    | 04/23/96                       | Lau, et al.                             | 514      | 418                        | 05/22/95 |
|   | GD        | 5  | 5 | 2 | 1 | 2                            | 1               | 3    | 05/28/96                       | Presit, et al.                          | 514      | 443                        | 08/29/94 |
|   | GE        | 5  | 5 | 5 | 0 | 1                            | 4               | 2    | 08/27/96                       | Ducharme et al.                         | 514      | 365                        | 05/08/95 |
|   | GF        | 5  | 5 | 5 | 2 | 4                            | 2               | 2    | 09/03/96                       | Gauthier, et al.                        | 514      | 368                        | 01/11/95 |
|   | GG        | 5  | 6 | 0 | 4 | 2                            | 5               | 3    | 02/18/97                       | Lau, et al.                             | 514      | 415                        | 05/22/95 |
|   | GH        | 5  | 8 | 3 | 9 | 7                            | 8               | 0    | 06/17/97                       | Lau, et al.                             | 514      | 419                        | 05/22/95 |
| FOREIGN PATENT DOCUMENTS  |           |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   |           | DOCUMENT NUMBER  |   |   |   |                              |                 | DATE | COUNTRY                        | CLASS                                   | SUBCLASS | TRANSLATION                |          |
|   |           |  |   |   |   |                              |                 |      |                                |   |          | YES                        | NO       |
|   | GI        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GJ        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GK        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GL        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GM        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |           |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
| <i>MM</i>   | GN        | Anti-inflammatory Drugs and Their Mechanism of Action J.R. Vane, et al. Inflamm. Res. 47, Supplement 2 (1898). |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GO        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GP        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GO        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
|   | GR        |  |   |   |   |                              |                 |      |                                |   |          |                            |          |
| EXAMINER  | <i>MM</i> |  |   |   |   |                              | DATE CONSIDERED |      |                                |   |          | <i>6/30/04</i>             |          |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |           |  |   |   |   |                              |                 |      |                                |   |          |                            |          |

| FORM PTO-1449<br>(REV. 7-80)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE  |      | ATTY. DOCKET NO.:<br>200.1078CON4     | SERIAL NO.: Not Yet Known<br>10/056,348 |                             |                            |
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| LIST OF PRIOR ART CITED BY APPLICANT<br>(Use several sheets if necessary) |    |   |      | APPLICANT(S): Ronald M. BURCH, et al. |   |                             |                            |
|   |    |   |      | FILING DATE: Not Yet Known            |   | GROUP: Not Yet Known<br>639 |                            |
| U.S. PATENT DOCUMENTS   |    |   |      |                                       |   |                             |                            |
| *EXAMINER INITIAL   |    | DOCUMENT NUMBER   | DATE | NAME                                  | CLASS                                   | SUBCLASS                    | FILING DATE IF APPROPRIATE |
| HD  |    |   |      |                                       |   |                             |                            |
| HE  |    |   |      |                                       |   |                             |                            |
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| HG  |    |   |      |                                       |   |                             |                            |
| HH  |    |   |      |                                       |   |                             |                            |
| HI  |    |   |      |                                       |   |                             |                            |
| HJ  |    |   |      |                                       |   |                             |                            |
| HK  |    |   |      |                                       |   |                             |                            |
| FOREIGN PATENT DOCUMENTS  |    |   |      |                                       |   |                             |                            |
|   |    | DOCUMENT NUMBER   | DATE | COUNTRY                               | CLASS                                   | SUBCLASS                    | TRANSLATION                |
|   |    |   |      |                                       |   |                             | YES NO                     |
| HL  |    |   |      |                                       |   |                             |                            |
| HM  |    |   |      |                                       |   |                             |                            |
| HN  |    |   |      |                                       |   |                             |                            |
| HO  |    |   |      |                                       |   |                             |                            |
| HP  |    |   |      |                                       |   |                             |                            |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)    |    |   |      |                                       |   |                             |                            |
| <i>MM</i>   | HQ | Rorarius et al., "Non-Steroidal Anti-Inflammatory Drugs for PostOperative Pain Relief," <i>Curr. Opin. in Anaesthesiology</i> , 7, 358-362. (1894)  |      |                                       |   |                             |                            |
|   | HR | Hanses et al. "Pharmacokinetics and Drug input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration," <i>Arzneim.-Forsch./Drug Res.</i> , 46(I), Nr. 1, 157-63. (1996) |      |                                       |   |                             |                            |
|   | HS | Merck Index, Twelfth Edition, Merck & Co. Publishers, page 1194. (1996)   |      |                                       |   |                             |                            |
| <i>MM</i>   | HT | Goodman and Gilman's: <i>Pharmaceutical Basis of Therapeutics</i> , "Chapter 22: Opioid Analgesics and Antagonists", MacMillan Publishing Co., Inc., pp-494-497, esp. Table 22-1, p. 496. (1980)                          |      |                                       |   |                             |                            |
| EXAMINER <i>MM</i>  |    |   |      | DATE CONSIDERED <i>6/30/04</i>        |   |                             |                            |

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|---|--|--|---------|-------|-----------|-------------|-------------------------|--|--------------------------------------|--|--------------------------------------|--|
| O I P E<br>DEC 02 2002<br>U.S. PATENT & TRADEMARK OFFICE<br>LIST OF PRIOR ART CITED BY APPLICANT<br>(Use several sheets if necessary)   |  |  |         |       |           |             |                         |  | APPLICANT(S):Ronald M. BURCH, et al. |  |                                      |  |
|   |  |  |         |       |           |             |                         |  | FILING DATE:<br>September 17, 1998   |  | GROUP: 1627 1639                     |  |
| FOREIGN PATENT DOCUMENTS  |  |  |         |       |           |             |                         |  |                                      |  |                                      |  |
|   | DOCUMENT NUMBER  | DATE   | COUNTRY | CLASS | SUBCLAS S | TRANSLATION |                         |  |                                      |  |                                      |  |
|   |  |  |         |       |           | YES         | NO                      |  |                                      |  |                                      |  |
| AA  | 0 6 5 4 2 6 3  | 05/24/95   | EP (A1) | A61K  | 31/135    |             |                         |  |                                      |  |                                      |  |
| AB  | 0 6 5 4 2 6 3  | 05/24/95   | EP (B1) | A61K  | 31/135    |             |                         |  |                                      |  |                                      |  |
| AC  | 9 7 1 7 9 7 8  | 05/22/97   | WO      | A61K  | 33/00     |             |                         |  |                                      |  |                                      |  |
| AD  | 9 7 2 5 9 8 8  | 07/24/97   | WO      | A61K  | 31/495    |             |                         |  |                                      |  |                                      |  |
| AE  | 9 7 3 2 8 5 7  | 09/12/97   | WO      | C07D  | 241/104   |             |                         |  |                                      |  |                                      |  |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |  |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AF  | Dray et al. New Pharmacological Strategies for Pain Relief. <u>Annual Review of Pharmacology &amp; Toxicology</u> , 36, pp. 253-280. (1996).   |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AG  | Brasseur. L. Revue des therapeutiques pharmacologiques actuelles de la douleur. <u>Drugs</u> , 53 Suppl 2, pp. 10-17. (1997)   |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AH  | Rang et al. New molecules in analgesia. <u>British Journal of Anesthesia</u> , 75, pp. 145-156 (1995)  |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AI  | Beaver, WT. Combination Analgesics. <u>American Journal of Medicine</u> , 77 (Suppl 3A), pp. 38-53. (1984).  |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AJ  | Beaver, WT. Chapter 29: Nonsteroidal Antiinflammatory Analgesics and Their Combinations with Opioids. In <u>Evaluation and Treatment of Chronic Pain</u> , 2 <sup>nd</sup> ed.; William & Wilkins pp. 363-383. (1992).                 |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AK  | Goodman & Gilman's. <u>The Pharmacological Basis of Therapeutics</u> , 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp 535 and 551-552.   |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AL  | Picard et al. Ketorolac potentiates morphine in postoperative patient-controlled analgesia. <u>Pain</u> , 73, 3 pp. 401-406. (1997).   |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AM  | Etches et al. Continuous Intravenous Administration of Ketorolac Reduces Pain and Morphine Consumption After Total Hip or Knee Arthroplasty. <u>Anesthesia &amp; Analgesia</u> , 81 (6), pp. 1175-1180. (1995).                        |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AN  | Hodsman et al. The morphine sparing effects of diclofenac sodium following abdominal surgery. <u>Anaesthesia</u> , 42(9), pp. 1005-1008. (1987).   |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AO  | Kaasalainen et al. Developments in the treatment of cancer pain in Finland: The third nation-wide survey. <u>Pain</u> , 70, 2-3, pp. 175-183. (1997).  |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AP  | Sunshine et al. Analgesic Efficacy of a Hydrocodone with Ibuprofen Combination Compared with Ibuprofen Alone for the Treatment of Acute Postoperative Pain. <u>Journal of Clinical Pharmacology</u> , 37 (10), pp. 908-915. (1997).    |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AQ  | Insel. Chapter 27: Analgesic-Antipyretic and Anti-Inflammatory Agents. In Hardman, ed., <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp. 654-655. (1996). |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AR  | Polisson. Non-steroidal Anti-Inflammatory Drugs: Practical and Theoretical Consideration in Their Selection. <u>The American Journal of Medicine</u> , 100 (Suppl 2A), pp. 2A-31S - 2A-36S. (1996).                                    |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AS  | Vane, J. Towards a better aspirin. <u>Nature</u> , 367, pp. 215-216. (1994).   |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| AT  | Simon, L.S. Nonsteroidal Antiinflammatory Drugs and Their Effects: The Importance of COX 'Selectivity'. <u>Journal of Clinical Rheumatology</u> , 2 (3), pp. 135-140. (1996).  |  |         |       |           |             |                         |  |                                      |  |                                      |  |
| EXAMINER  |  |  |         |       |           |             | DATE CONSIDERED 4/30/04 |  |                                      |  |                                      |  |
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| FORM PTO-1449<br>(REV. 7-80)  |   | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.:<br>200.1079US | SERIAL NO.: 09/154,354<br>10/056,348 |
| LIST OF PRIOR ART CITED BY APPLICANT<br><br>(Use several sheets if necessary) |   | APPLICANT(S): Ronald M. BURCH, et al.                      |                                 |                                      |
|   |   | FILING DATE: September<br>17, 1998                         | GROUP: 1627<br>1639             |                                      |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)        |   |  |                                 |                                      |
| BA  | Van Ryn et al. Selective cyclooxygenase-2 Inhibitors: pharmacology, clinical effects, and therapeutic potential. <u>Expert Opinion On Investigational Drugs</u> . pp. 609-614. (1997).  |  |                                 |                                      |
| BB  | Vane et al. New Insights into the mode of action of anti-Inflammatory drugs. <u>Inflammation Research</u> . 44, (No.1), pp 1-10 (1995).   |  |                                 |                                      |
| BC  | Engelhardt. Meloxicam: A Preferential Inhibitor of COX-2. <u>British Journal of Rheumatology</u> . 34, Abstract Suppl. 1, p. 48. (1995). Abstract.  |  |                                 |                                      |
| BD  | Lane, N.E. Pain Management in Osteoarthritis: The Role of COX-2 Inhibitors. <u>Journal of Rheumatology</u> . Vol. 24, Suppl 49, pp. 20-24. (1997).  |  |                                 |                                      |
| BE  | Boyce et al. L-745,337: A Selective Inhibitor of Cyclooxygenase-2 Elicits Antinociception But Not Gastric Ulceration In Rats. <u>Neuropharmacology</u> Vol. 33, pp. 1609-1611. (1994).  |  |                                 |                                      |
| BF  | Donelly et al. COX-II Inhibitors - a new generation of safer NSAIDS? <u>Alimentary Pharmacology and Therapeutics</u> , 11, 2, pp. 227-236. (1997).  |  |                                 |                                      |
| BG  | Wallace, J.L. Nonsteroidal Anti-Inflammatory Drugs and Gastroenteropathy: The Second Hundred Years. <u>Gastroenterology</u> , 112, 3, pp. 1000-1016. (1997).  |  |                                 |                                      |
| BH  | Robinson, D.R. Regulation of Prostaglandin Synthesis by Antiinflammatory Drugs. <u>J Rheumatol</u> , 24, Suppl. 47, pp. 32-39. (1997).  |  |                                 |                                      |
| BI  | Tannenbaum et al. An Evidence-Based Approach to Prescribing NSAIDS in Musculoskeletal Disease: A Canadian Consensus. <u>Canadian Medical Association Journal</u> , 155, 1, pp. 77-88. (1996).   |  |                                 |                                      |
| BJ  | Mehlisch et al. Analgesic Efficacy and Plasma Levels of a Highly Selective Inhibitor of COX-2 (SC-58635, SC) in Patients with Postsurgical Dental Pain. <u>Journal of Clinical Pharmacology</u> , 37, 9, 863. (1997). Abstract.   |  |                                 |                                      |
| BK  | Dammann. Selective COX-2 Inhibition: Its Relevance for NSAID-Gastrointestinal Toxicity. <u>Gut</u> , 39, Suppl. 3, A151. (1996). Abstract.  |  |                                 |                                      |
| BL  | Penning et al. Synthesis and Biological Evaluation of the 1, 5 -dihydropyrazole class of cyclooxygenase-2 Inhibitors: Identification of 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide (SC-58635, Celecoxib). <u>Journal Of Medicinal Chemistry</u> , 40(9), 1347-65. (1997). |  |                                 |                                      |
| BM  | Lipsky et al. Outcome of Specific COX-2 Inhibition in Rheumatoid Arthritis. <u>Journal Of Rheumatology</u> , 24 Suppl 49, pp. 9-14. (1997).   |  |                                 |                                      |
| BN  |   |  |                                 |                                      |
| BO  |   |  |                                 |                                      |
| BP  |   |  |                                 |                                      |
| BQ  |   |  |                                 |                                      |
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| BT  |   |  |                                 |                                      |
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Sheet 1 of 1

FORM PTO-1449  
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U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:  
200.1079US

SERIAL NO.:  
09/154,364 10/056,348

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP:  
1627 1639

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL |  | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|-------------------|--|-----------------|------|------|-------|----------|----------------------------|
| AA                |  |                 |      |      |       |          |                            |
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FOREIGN PATENT DOCUMENTS

|    |               | DOCUMENT NUMBER | DATE      | COUNTRY | CLASS  | SUBCLASS | TRANSLATION |    |
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|    |               |                 |           |         |        |          | YES         | NO |
| AM | 0 7 3 4 2 7 5 | 11/04/1997      | Australia | C07D    | 261/08 |          | →           | →  |
| AN |               |                 |           |         |        |          |             |    |
| AO |               |                 |           |         |        |          |             |    |
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| <i>W. C. M.</i> | 6/30/04         |

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